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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,020	02/02/2005	Atsushi Ozaki	05273.0095-00000	7467
22852 7590 08/02/2007 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER HENLEY III, RAYMOND J	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 08/02/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/523,020

Applicant(s)

OZAKI ET AL.

Examiner

Raymond J. Henley III

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

CLAIMS 20-24 ARE PRESENTED FOR EXAMINATION

Applicants' amendment filed May 15, 2007 has been received and entered into the application. Accordingly, claims 1-19 have been canceled and claims 20-24 have been added.

Applicants' amendments have rendered moot the rejections set forth in the previous Office action not reiterated herein and such rejections are hereby withdrawn. The following rejection constitutes the totality of issues remaining in the present application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejection - 35 USC § 103

Claims 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa et al., (U.S. Patent No. 5,753,677) in view of Gheorghiade et al., (Drugs of the Future reference), each of record, for the reasons of record as set forth in the previous Office action dated February 20, 2007 at pages 5-6, as applied to claims 1-19, which reasons are here incorporated by reference.

Applicants' remarks at pages 4-6 of their amendment have been carefully considered, but fail to persuade the Examiner of error in his determination of obviousness.

The present issue turns on whether as the congestive heart failure patient of Ogawa et al., it would have been obvious to treat severe congestive heart failure, "CHF", i.e., NYHA Class IV, as compared to other, less severe levels of CHF, by administering the claimed compound, i.e., tolvaptan a vasopressin antagonist.

Art Unit: 1614

Applicants have traversed the Examiner's position by pointing to the known definition of NYHA Class IV and to the recognition in the art that patients suffering therefrom are in need of different, "more-than-ordinary" treatment as compared to patients suffering from other, less severe forms of CHF. Applicants have urged that one of ordinary skill in the art would have had no reason to expect the presently claimed compound as being useful in NYHA Class IV CHF.

This does not persuade the Examiner of non-obviousness because even in NYHA class IV, "ordinary" CHF treatments, such as diuretics, find utility and in this role, it is not seen unobvious from the art relied on to have employed the presently claimed compound, known to be effective as a diuretic in CHF patients, for the treatment of CHF-associated edema in any of the NYHA classes, including class IV as presently claimed.

In support of the position that "ordinary" agents were additionally used in class IV patients, the Examiner relies on Applicants' remarks at page 6 of their amendment, citing *Remme and Swedberg*, "for NYHA Class IV patients, it is necessary to consider special treatment, such as heart transplantation, in addition to ordinary treatment for CHF such as ACE inhibitors...".

Accordingly, for the reasons above, the claims are deemed properly rejected and none are deemed in condition for allowance.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

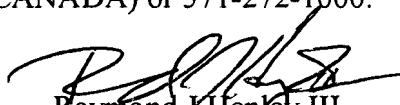
Art Unit: 1614

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Raymond J Henley III
Primary Examiner
Art Unit 1614

July 30, 2007